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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,226	02/13/2002	Naoya Yamato	219107US0	4816

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EXAMINER

KIM, VICKIE Y

ART UNIT PAPER NUMBER

1614

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/073,226

Applicant(s)

YAMATO ET AL.

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 5-11, 21-23, 26-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 12-20, 24, 25 and 33-41 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

RCE acknowledged

A request for continued examination(RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on Dec 10, 2004 has been entered.

Status of Application

1. Acknowledgement is made of amendment filed 12/10/2004. Upon entering the amendment, the claim 1 is amended.
2. The claims 1-41 are pending. The elected claims 1-4 and 12-20, 24-25, 33-41 whose subject matter are drawn to a compound are presented for the examination.

Claim Rejections - 35 USC §102/ 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 12-20, 24-25, 33-41 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hofrichter et al (US 5591424).

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The claims, now amended, are drawn to a compound having general formula recited in the instant claim 1 wherein R1 and R2 independently represent a hydrocarbon group having 1 to 26 carbon atoms, R3 represents a hydrocarbon group having 8-10 carbon atoms.

The claims 3-4 are specifically directed to N-2-ethylhexanoyl (or octanoyl or decanoyl)-L-glutamic acid dibutylamide.

Hofrichter(US'424, hereafter) teaches N-acyl glutamic acid amides having same generic formula wherein R1 and R2 independently represent a hydrocarbon group having 1 to 26 carbon atoms, R3 represents a hydrocarbon group having 1-26 carbon atoms, preferably 6-22 carbon atoms, see column 4 lines 32-51.

Furthermore, US'424 exemplifies N-lauroyl-glutamic acid dibutyl amide or N-stearoyl-glutamic acid dibutyl amide as the preferred species, see column 4, lines 54 and 60.

Thus, the claimed compound would have been readily envisaged by skilled artisan because preferred compounds(species) of US'424 patent that has R3 substitution of C=6-22 well embraces the scope of the claimed invention (i.e. R3 substitution of C=8-10).

Although the claimed species (i.e. N-2-ethylhexanoyl (or octanoyl or decanoyl)-L-glutamic acid dibutylamide) are not specifically mentioned by US'424 patent, the difference between the teaching of US'424 (i.e. lauroyl(C=12) and stearoyl(C=18)) and the instant claims (i.e. ethylhexanoyl(C=8), octanoyl(C=8) or decanoyl(C=10)) is not patentably distinguishable whereas the difference are close enough to any skilled

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artisans to modify. Especially, the techniques and skills to make the said modifications are well taught by the cited patent, see the variable carbon numbers in preferred species exemplified in column 4.

The elongation or elimination of alkyl groups are well within skilled level, and conventionally and routinely practiced in the pharmaceutical industry. Thus, the claimed species are readily envisaged or clearly considered as obvious variants from the teaching of the patented disclosure, absent evidence to the contrary.

As to claims 16-20 and 37-41, the minor variations such as purification, chemical synthesis, isolation, crystal or hydrate form are considered to be conventional knowledge wherein the techniques and skills are well within the skilled level of the artisan and commonly practiced in the art(see PTO-892, evidentiary documents).

One would have been motivated to make such species because it is always desired to have extended family of the class because extended selection option increases industrial values and provides benefits to users due to easy accessibility and the competition which allow cost-effective manufacture. One would have been motivated to do so, with reasonable expectation of success, because the techniques and skills are suggested by the cited reference and also considered to be well within skilled level of the artisan. The teaching of the cited reference is particularly pertinent and relevant because the generic formula with the suggestion of the possible substitution to cover the claimed species is well taught in the cited reference. Thus, one would have been motivated to modify the teaching of this references because they are drawn to same technical fields (constituted with same ingredients and share common

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utilities, and pertinent to the problem which applicant concerns about. MPEP

2141.01(a).

Response to Arguments

4. Applicant's arguments filed 11/25/03 have been fully considered but they are not persuasive. Applicant's response provides the arguments that proves the unexpected superior gelling effect(intended use) of the claimed compound and the improvement made in the cosmetic/pharmaceutical industry. The compound itself does not have gelling ability whereas the compound has to be formulated into a composition to exert gelling activity as shown in the test included in the remark section(see page 12).

The patentability of the claimed invention(i.e. N-2-ethylhexanoyl (or octanoyl or decanoyl)-L-glutamic acid dibutylamide) should be discussed based on the comparison with other compound(i.e. exemplifies N-lauroyl-glutamic acid dibutyl amide) and applicant should provide the supporting evidence why the elongation of such alkyl groups(e.g. C=10 to C=12) are patentably distinct and unobvious over the teaching of prior art wherein cited patent teaches that preferred species are not limited to C=6-22(see column 4, line 45), whereas applicant fails to show the evidence to support this argument.

However, applicant should be reminded that the examination is limited to the elected invention that is drawn to a compound not a composition(gal composition) whereas gelling ability does not render the claimed invention(i.e. compound) patentable, and therefore, applicant's argument is not persuasive in this case. Until the elected

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invention is found to be allowable, applicant's argument should be limited to the compound.

The test for obviousness is not whether the features of a secondary teaching may be bodily incorporated into the structure of the primary teaching; nor is it that the claimed invention must be expressly suggested in the reference. Rather, the test is what the teachings of the reference would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

5. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., gel composition) are not elected invention and are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579(fax: 571-273-0579). The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Low Christopher can be reached on 571-272-0584. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and (703) 872-9306 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

VICKIE KIM
PRIMARY EXAMINER

Vik
March 15, 2005
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